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10/552,089

10/04/2005

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ROCHE-P003

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EXAMINER

OMGBA, ESSAMA

ART UNIT

PAPER NUMBER

3726

MAIL DATE

DELIVERY MODE

12/02/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/552,089 | Applicant(s) HOENES ET AL. | |
| | Examiner Essama Omgba | Art Unit 3726 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/21/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because in line 1, the phrase "The invention relates to" should be deleted. Correction is required. See MPEP § 608.01(b).

Claim Objections

2. Claims 1-20 are objected to because of the following informalities: in claims 1 and 18, line 1, "Method" should read --A method--; in claims 2-17, line 1, "Method" should read --The method--; in claim 19, line 1, "Combined" should read --A combined--; and in claim 20, line 1, "Combined" should read --The combined--. Appropriate correction is required.
3. Reference characters corresponding to elements recited in the detailed description of the drawings and used in conjunction with the recitation of the same element or group of elements in the claims should be deleted so as to avoid confusion with other numbers or characters which may appear in the claims.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 1-17, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the band-shaped support material" in line 5. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the material" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 13 recites the limitations "the coating" and "the material" in line 2. There is insufficient antecedent basis for these limitations in the claim.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Yuzhakov et al. (US 2002/0168290).

With regards to claim 1, Yuzhakov et al. discloses a method for producing combined puncturing and measuring devices for detection of an analyte in liquid comprising a support 8 and a detection element 12 (see abstract and paragraph [0010]), the method comprising forming recesses (spaces between elements 212 in figure 6A) which define puncturing points 212 on one face of a band shape support material, applying a detection element 206, and separating individual puncturing/measuring disposable bodies singly from the band-shaped support material at separating lines (fig. 6A and paragraph [0108]).

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Regarding claim 2, see channel 238.

Regarding claims 3-5, see figures 6A-6C.

Regarding claim 6, see channel 238 and paragraph [0082].

Regarding claims 7 and 8, Official Notice is taken in that depressions with a depression base which has a triangular contour are old and well known in the art, as is forming depressions by punching or cutting out material

Regarding claim 9, see figure 6A.

Regarding claim 10, Applicant should note that it is conventional to ground such puncturing points.

Regarding claims 12, 13 and 16, see paragraph [0082].

Regarding claims 14, 15 and 17, see figure 6A.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 11 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuzhakov et al. in view of Kuhr et al. (US Patent 7,396,334).

Regarding claims 11, 18 and 19, Yuzhakov et al. discloses a method for producing combined puncturing and measuring devices comprising forming puncturing points 112 on a band-shaped support material, sterilizing the puncturing points and

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applying a detection element to the band-shaped support material as shown above Yuzhakov et al. does not disclose providing a soft plastic cover covering the puncturing points. However it is known to cover such puncturing points with soft plastic cover during manufacture of the devices as attested by Kuhr et al. see column 8, lines 41-65. therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made, to have provided soft plastic cover covering the puncturing points in the method of Yuzhakov et al., in light of the teachings of Kuhr et al., as is known in the art.

Regarding claim 20, applicant should note that the channels in the method of Yuzhakov et al. can be produced by embossing.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Essama Omgba whose telephone number is (571) 272-4532. The examiner can normally be reached on M-F 9-6:30, 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Bryant can be reached on (571) 272-4526. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Essama Omgba/
Primary Examiner, Art Unit 3726

eo
November 24, 2008